



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL - 2 1999

6537 '99 JUL -6 P1:40

. Ms. Jennifer K. Muir
8219 N. 43rd Drive
Glendale, Arizona 85302-6602

Dear Ms. Muir:

Thank you for your recent inquiry to Senator John McCain, regarding actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation. Senator McCain has asked us to respond directly to you.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients" FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

98N 1038

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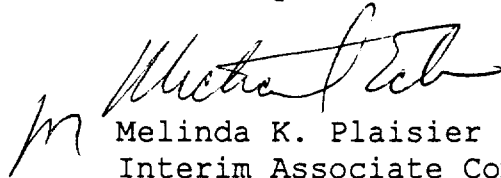
Page 2 - Ms. Jennifer K. Muir

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

In regard to irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,

A handwritten signature in cursive script, appearing to read "Melinda K. Plaisier".

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosures

cc: The Honorable John McCain
United States Senate
Washington, D.C. 20510-0303

Dockets Management Branch
(98N-1038)

JOHN McCAIN

ARIZONA

CHAIRMAN, COMMITTEE ON COMMERCE,
SCIENCE, AND TRANSPORTATION

COMMITTEE ON ARMED SERVICES

COMMITTEE ON INDIAN AFFAIRS

United States Senate

May 26, 1999

241 RUSSELL SENATE OFFICE BUILDING
WASHINGTON, DC 20510-0303
(202) 224-2235

1839 SOUTH ALMA SCHOOL ROAD
SUITE 375
MESA, AZ 85210
(602) 491-4300

2400 EAST ARIZONA
BILTMORE CIRCLE
SUITE 1150
PHOENIX, AZ 85016
(602) 952-2410

450 WEST PASEO REDONDO
SUITE 200
TUCSON, AZ 85701
(520) 670-6334

TELEPHONE FOR HEARING IMPAIRED
(202) 224-7132
(602) 952-0170

Ms. Diane Thompson
Legislative Affairs
Food and Drug Administration
5600 Fishers Lane, Room 15-55
Rockville, Maryland 20857-0001

Dear Diane:

I have enclosed inquiries which I have received from several of my constituents from Arizona.

I would greatly appreciate it if you would review this material within existing rules, regulations and ethical guidelines. Please send a prompt response addressing this issue to each of these constituents, and provide me with copies of the responses for my records.

PLEASE SEND THE COPY TO THE ATTENTION OF: Brian Roth in my Washington office, 241 Russell Senate Office Building, Washington, D.C. 20510. Thank you very much for your kind assistance and cooperation.

Sincerely,



John McCain
United States Senator

JM/ina
Enclosures

No 99-3759

L. 111 2800

May 6, 1999

The Honorable John McCain
241 Russell Senate Office Building
Washington, D.C. 20510

Senator,

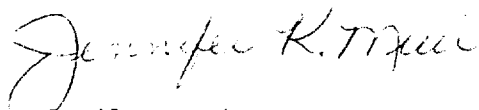
I have recently been made aware of a frightening development at the Food and Drug Administration. Under pressure from food manufacturers and supporters of the nuclear industry, the FDA is considering a rule that would remove labeling requirements for foods treated with radiation. The public only has until May 18 to voice its objections to this rule.

Currently, any food treated with radiation during the production process is labeled with a symbol known as a radura (the international symbol for irradiated foods) and either a statement saying "treated with radiation" or "treated by irradiation." The rule before the FDA would allow manufacturers to sell any and all irradiated foods to the consumer with nary a mention of the use of radiation during processing. This is bad for consumers.

Despite the fact that the FDA has determined that radiation is safe for food, many consumers, including myself, do not want to eat foods treated with radiation. Radiation changes the texture, taste, nutritional value, and chemical composition of foods. Radiation creates a heretofore unseen class of unique radiolytic products that have never been tested for their possible carcinogenic effects on humans. These are things that I do not want to put into my body.

This is a clear cut issue of a consumer being able to know what is in their food. We know what the fat, protein, carbohydrate, and vitamin content is in our food, why can we not know whether our food has been treated with radiation emanating from some of the most deadly substances known to man? I implore you, as a constituent and a friend, to write a letter to the FDA about this issue and ask them why your constituents should be kept in the dark about whether their food has been irradiated and why the comment period has been so short. Enclosed you will find the letter that I wrote to the FDA about this issue. I hope it is helpful in formulating your own comments.

Sincerely,



Jennifer K. Muir
8219 N. 43rd Drive
Glendale, AZ 85302-6602

Encl: Letter to FDA

May 6, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-1038, Irradiation in the Production,
Processing, and Handling of Food

To whom it may concern:

I support the recommendation by the Center for Science in the Public Interest regarding labeling of irradiated foods:

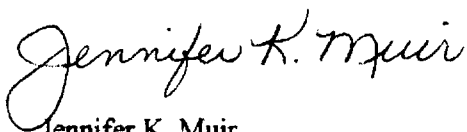
"any foods, or any foods containing ingredients that have been treated by irradiation, should be labeled with a written statement on the principal display panel indicating such treatment. The statement should be easy to read and placed in close proximity to the name of the food and accompanied by the international symbol. If the food is unpackaged, this information should be clearly displayed on a poster in plain view and adjacent to where the product is displayed for sale."

Like other labels, irradiation labels are required by the FDA to be truthful and not misleading. I believe that the terms "treated with radiation" or "treated by irradiation" should be retained. Any phrase involving the word "pasteurization" is misleading because pasteurization is an entirely different process of rapid heating and cooling.

I recognize the radura as information regarding a material fact of food processing. The requirement for irradiation disclosure (both label and radura) should not expire at any time in the future. The material fact of processing remains. Even if some consumers become familiar with the radura, new consumers (e.g., young people, immigrants) will not be. The symbol should be clearly understandable at the point of purchase for everyone. If there is no label, consumers will be misled into believing the food has not been irradiated.

I urge you to extend the comment period past its current end date of May 18 to allow more concerned citizens the time to write in about this issue. Also, please place the comments received on the Internet so that the public can be informed about who is participating in this comment process.

Sincerely,



Jennifer K. Muir
8219 N. 43rd Drive
Glendale, AZ 85302-6602
(623) 842-2529